

van Lengerich - Serial No. 09/233,443
AMENDMENT AFTER FINAL REJECTION UNDER 37 C.F.R. 1.116
AND SUMMARY OF TELEPHONIC INTERVIEW WITH EXAMINER

REMARKS

Upon entry of this Amendment, Claims 21-22, 26, 28-29, 46-55, 57, 61-67, and 96-109 are pending herein. By this Amendment, non-elected Claims 1-20, 23-25, 27, 30-45, 56, 58, and 68-95, are canceled, without prejudice or disclaimer; Claims 21-22, 26, 46, and 103 are amended; and new Claims 107-109 are added. Support for the claim amendments and new claims is found in the specification at, *inter alia*, page 10, lines 10-15 and page 11, lines 15-18. No new matter is added by this Amendment.

The claim amendments are identical to those in the Amendment After Final Rejection filed on June 5, 2003. The Examiner indicated in the Advisory Action that these claim amendments would be entered.

Applicants thank Examiner Ed Webman for the courtesies extended to their representative during the July 17, 2003 telephone conference. Applicants' separate record of the telephone interview is set forth in the foregoing amendments and the following remarks.

I. RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS

Upon entry of this Amendment, the claims readable upon the elected species are Claims 21-22, 26, 29, 47-52, 54-55, 57, 66-67, 96-97, 99, and 101-109.

Contrary to the assertion in the Office Action, Applicants still traverse the restriction requirement and set forth reasons why the restriction requirement is in error in the Amendment filed on July 1, 2002. To reduce the number of issues, however, Applicants have canceled the non-elected method claims, without prejudice or disclaimer. For the reasons set forth in the Amendment filed on July 1, 2002, Applicants respectfully request that product Claims 28, 46, and 61-65 also be examined.

Applicants responded without traverse on November 22, 2002 to the election of species requirement dated November 6, 2002 regarding the hydrophobic agent. Once the pending claims are found allowable search and examination must continue as to the non-

van Lengerich - Serial No. 09/233,443
AMENDMENT AFTER FINAL REJECTION UNDER 37 C.F.R. 1.116
AND SUMMARY OF TELEPHONIC INTERVIEW WITH EXAMINER

elected species of encapsulants, such as enzymes and probiotics. Thus, Claims 53, 98, and 100 have not been canceled.

II. FORMAL MATTERS

Claims 21-22, 47-52, 54, 66-67, 96-97, 99, and 101-106 were rejected under 35 U.S.C. 112, second paragraph, as assertedly being indefinite.

Applicants respectfully note that the word "substantially" is not indefinite. See MPEP 2173.05(b)(D).

In support of the Examiner's position that the term "substantially" is indefinite, he cited one case from a district court, *E.W. Bliss v. Cold Metal Process Co.*, 174 F. Supp. 99, 122 USPQ 238 (N.D. Ohio 1959). However, the Examiner's assertion that the term "substantially" may be "as much as 49%" is not in accordance with the particular facts of that case. In *E.W. Bliss*, the district court relied upon the statements in the file history to hold that the claimed limitation "driven substantially by tension on the strip" does not extend to tension supplying 49% of the total power. See *E.W. Bliss*, 174 F. Supp. at 125. In addition, the court noted that the word "substantial" does not connote small or meager. Id. Rather, it includes the "high range of principally or entirely." Id.

In the previous Amendment, Applicants cited numerous recent cases from the Federal Circuit, which has authority over district courts such as that in *E.W. Bliss*, to demonstrate that the term "substantially" is definite without any quantitative or numerical definition, so long as one of ordinary skill in the art understands what is claimed. See *York Products, Inc. v. Central Tractor Farm & Family Center*, 99 F.3d 1568, 1573 (Fed. Cir. 1996); *Pall Corp. v. Micron Seps.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995); *Andrew Corp. v. Gabriel Elecs. Inc.*, 847 F.2d 819 (Fed. Cir. 1988). One of ordinary skill in the art would understand that the term "substantially" as claimed means "principally or entirely". See, for example, page 7, lines 13-25, page 13, lines 24-31, page 14, line 28 - page 15, line 4, and page 27, lines 18-23 of the present specification. Accordingly, the

van Lengerich - Serial No. 09/233,443

AMENDMENT AFTER FINAL REJECTION UNDER 37 C.F.R. 1.116
AND SUMMARY OF TELEPHONIC INTERVIEW WITH EXAMINER

scope of Claims 21-22, 47-52, 54, 66-67, 96-97, 99, and 101-106 would be reasonably ascertainable to one of ordinary skill in the art when read in light of the specification.

Thus, the requirements of 35 U.S.C. 112, second paragraph, are satisfied.

Applicants thank Examiner Webman for indicating during a July 17, 2003 telephone interview that this rejection is overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

III. REJECTION UNDER 35 U.S.C. 103(a)

Claims 21-22, 26, 29, 47-52, 54-55, 57, 66-67, 96-97, 99, and 101-106 were rejected under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,320,669 (Lim et al.) in view of U.S. Patent No. 5,716,615 (Cavaliere Vesely et al.). This rejection is respectfully traversed.

A. LIM ET AL.

Lim et al. discloses a biodegradable thermoplastic composition made of a cereal grain, such as durum wheat, and which may also contain lubricant additives, such as fatty acids or vegetable oils (col. 6, lines 7-26). The cereal grain may be nutritionally reinforced with vitamins or minerals (col. 3, lines 35-39). The edible composition may also contain an edible flavoring agent or an antimicrobial agent (col. 7, lines 5-14). There is no disclosure regarding the amount of vitamins, minerals, flavoring agent, or antimicrobial agent.

The cereal grain compositions of Lim et al. are translucent, have a high degree of mechanical strength, and are water-resistant. The cereal grain-based thermoplastics may be suitable for making articles that are edible by a human or other animal "after use, as for example food containers, tablewares, and the like" (col. 2, lines 36-40, emphasis added). The edible composition may also be a packaging article that is consumed by the

van Lengerich - Serial No. 09/233,443
AMENDMENT AFTER FINAL REJECTION UNDER 37 C.F.R. 1.116
AND SUMMARY OF TELEPHONIC INTERVIEW WITH EXAMINER

user along with the "package contents" or may be a food article such as a snack food or pet food, where consumption of the article is desired (col. 9, lines 45-50).

The cereal grain compositions may be molded to provide such edible articles. In particular, the molded articles may be in the form of sheets, capsules, trays, bottles, and tubing. The molded articles may be used for packaging a substance, such as foods and drugs, that contain moderate amounts of water (col. 9, lines 1-19).

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1. Lim et al. Does Not Teach or Suggest An Encapsulant Uniformly Distributed in a Plasticized Matrix Material

During the July 17, 2003 telephone interview, Applicants' representative asserted that Lim et al. does not teach or suggest an encapsulated product comprising a substantially homogeneous mixture of: (1) at least one plasticized matrix material, (2) about 1 wt.% to about 85 wt.% of an encapsulant based upon the weight of the matrix material, wherein the encapsulant is at least substantially uniformly distributed in the at least one plasticized matrix material, and (3) a hydrophobic agent, as recited in Claim 21.

Applicants' representative argued that the packaging disclosed in Lim et al. constitutes food containers or drug capsules. The containers or capsules are strong and water-resistant, thereby degrading over time when exposed to moisture "such as from the atmosphere and the package contents" (col. 9, lines 28-30). The entire objective of Lim et al. is to provide an article that is strong, water-resistant, and that will remain substantially intact for an extended period of time. Thus, the articles of Lim et al., when used as edible packaging, are meant to contain contents such as foods and drugs having moderate amounts of water. Accordingly, the edible package and contents are separate entities that do not form a homogeneous mixture. Applicants also respectfully note that the definition of "package" in The American heritage Dictionary is a wrapped or boxed object or a "container in which something is packed for storage or transporting." There is

van Lengerich - Serial No. 09/233,443
AMENDMENT AFTER FINAL REJECTION UNDER 37 C.F.R. 1.116
AND SUMMARY OF TELEPHONIC INTERVIEW WITH EXAMINER

no teaching or suggestion in Lim et al. to uniformly distribute an encapsulant through the cereal grain composition.

During the July 17, 2003 telephone interview, the Examiner asserted that the Examples of Lim et al. disclose a dogbone article. However, none of the Examples discloses using a dogbone to encapsulate anything, much less uniformly distributing an encapsulant throughout the dogbone. In the Examples of Lim et al., the cereal grain residue obtained by extraction with an organic solvent, followed by drying, is mixed with water and then molded. There is no teaching or suggestion of homogeneously mixing an encapsulant, such as *lactobacillus* with the solvent treated cereal grain prior to molding. See Example 1, col. 10, lines 14-37. Moreover, in view of the teachings of Lim et al., one of ordinary skill in the art would not have been motivated to use the dogbone to encapsulate an encapsulant. The Examiner also indicated during the telephone interview that "caplets" are known drug delivery vehicles. However, as the Examiner acknowledged, Lim et al. does not disclose any "caplets". Furthermore, there is no motivation stemming from Lim et al. to formulate a dogbone or snack as a "caplet" to deliver a pharmaceutical, *lactobacillus*, or any other encapsulant as claimed.

2. Lim et al. Also Does Not Teach Or Suggest the Claimed Encapsulants

Lim et al. also does not teach or suggest the encapsulants recited in Claims 22 and 26. Further, Lim et al. does not teach or suggest an encapsulated product comprising an encapsulant selected from the group consisting of live *lactobacilli*, a probiotic, a prebiotic, and an enzyme, wherein a liquid encapsulant component comprising the encapsulant and a liquid plasticizer provides at least a substantial portion of liquid plasticizer for forming the at least one plasticized matrix material, as recited in Claim 104 and its dependent claims. Although Lim et al. discloses using water as a plasticizer, there

van Lengerich - Serial No. 09/233,443
AMENDMENT AFTER FINAL REJECTION UNDER 37 C.F.R. 1.116
AND SUMMARY OF TELEPHONIC INTERVIEW WITH EXAMINER

is no teaching or suggestion of a liquid encapsulant component comprising an encapsulant and a liquid plasticizer.

B. CAVALIERE VESELY ET AL.

Cavaliere Vesely et al. does not overcome the deficiencies of Lim et al. Cavaliere Vesely et al. discloses a pharmaceutical composition containing several different bacteria including *Streptococcus thermophilus* and *Lactobacillus plantarum* or *Lactobacillus casei*. The compositions may be made in conventional pharmaceutical forms, such as tablets, capsules, packets, or solutions (col. 3, lines 19-21).

There is no teaching or suggestion to package the pharmaceutical composition of Cavaliere Vesely et al. in the water-resistant, biodegradable cereal grain composition of Lim et al. Even if Lim et al. and Cavaliere Vesely et al. were properly combinable, which they are not, Applicants' claimed encapsulated product would not be obtained. At best, such a combination would yield a non-homogenous combination of an edible package made of a cereal grain composition that serves as a container for the bacteria composition. The combination would not result in a homogeneous mixture of at least one plasticized matrix material and an encapsulant, wherein the encapsulant is at least substantially uniformly distributed in the at least one plasticized matrix material as recited in Claim 21. Lim et al. discloses packaging for drugs, but simply does not teach or suggest forming a homogeneous mixture of a drug and the packaging material. See col. 9, lines 13-15.

Like Lim et al., Cavaliere Vesely et al. also does not teach or suggest a liquid encapsulant component comprising the encapsulant and a liquid plasticizer provides at least a substantial portion of liquid plasticizer for forming the at least one plasticized matrix material, as recited in Claim 104. There is no teaching or suggestion whatsoever in Lim et al. or Cavaliere Vesely et al. to admix a matrix material with a liquid *lactobacillus* encapsulant to form a plasticized matrix material. Thus, it would not have

van Lengerich - Serial No. 09/233,443
AMENDMENT AFTER FINAL REJECTION UNDER 37 C.F.R. 1.116
AND SUMMARY OF TELEPHONIC INTERVIEW WITH EXAMINER

been obvious for one of ordinary skill in the art to make the claimed encapsulated products in view of the combined teachings of Lim et al. and Cavaliere Vesely et al. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. DOUBLE PATENTING

To avoid any question of double patenting, Applicants will file a Terminal Disclaimer over U.S. Patent 6,500,463 B1 if required by the Examiner.

V. CONCLUSION

In light of the foregoing remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application. Any shortages in fees should be charged to, or any overpayment in fees should be credited to, Deposit Account No. 501032 (Docket #BVL-105).

Respectfully submitted,



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DATE: August 6, 2003 TELEFAX NO. 703-383-4804 872-9306
TO: Examiner ED WEBMAN
FROM: WARREN ZITLAU
SUBJECT: U.S. Serial No. 09/233,443

Further to our August 6, 2003 telephone conference, enclosed are COURTESY COPIES of the AMENDMENT AFTER FINAL REJECTION and PETITION FOR EXTENSION OF TIME filed on July 17, 2003 via certificate of facsimile. We received confirmation of these filings by the US PTO. As the date for obtaining an additional extension of time is August 17, we would like to know the status of the application by that time.

Please do not hesitate to contact me if you have any questions.

Regards,

Warren Zitlau

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